FEB 2 0 2002

K013547

## Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

**Submitter:**
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**Name of the Device:** Babycom™.

**Predicate Devices:** The Babycom™ is substantially equivalent to the Fetal Dopplex II, manufactured by Huntco Healthcare, Inc. (subject of K930200).

**Description of the Device:** The Babycom™ is a fetal ultrasonic heart rate monitor that is designed to transmit and receive ultrasonic energy into and from a pregnant woman by means of continuous wave doppler echoscopy. The Babycom™ is used to represent the fetal heart rate in an immediately perceptible form, i.e., a digital display of the rate in beats per minute (bpm) and by an audible beating signal of the same rate. The Babycom™ includes a transducer module for transmitting and receiving ultrasound signals and a signal analysis, control and display module, that we refer to as the base, that carries out all the other Babycom™ functions. The Babycom™ measures the fetal heart rate by determining the doppler shift between the transmitted and received signals. The differences between the Babycom™ and the predicate device raise no new issues of safety or effectiveness.

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Date

Jacob Levy

Dr. Jacob Levy, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2002

PMG Medical, Ltd.
% Dr. Eli M. Orbach
Managing Director
d.b.a. International Regulatory Consultants
POB 6718, Efrat 90435
ISRAEL

Re: K013547
Trade/Device Name: Babycom
Ultrasonic Fetal Heart Rate Monitor
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor
and accessories
Regulatory Class: II
Product Code: 85 KNG
Dated: February 4, 2002
Received: February 6, 2002

Dear Dr. Orbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications For Use (separate page):**



510(k) Number (if known) K013547

Device Name The Babycom

Indications For Use:

The Babycom™ is meant to be applied to a woman's abdomen during pregnancy in order to measure the fetal heart rate (FHR) as a general indicator of fetal well-being.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013547